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1. Your reference — CSM/68110/000

2. Patent application number *(The Patent Office will fill in this part)* — 0308938.0 — 17 APR 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Limbs and Things Limited
Sussex Street
St. Phillips
Bristol BS2 0RA

Patents ADP number *(if you know it)* — 8413130001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom (GB)

4. Title of the invention — Medical Training System

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

PAGE HARGRAVE
Southgate, Whitefriars
Lewins Mead
BRISTOL BS1 2NT

Patents ADP number *(if you know it)* — 05996483001

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Yes

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Continuation sheets of this form	-
Description	10
Claim(s)	4
Abstract	1
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Priority documents	-
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11. I/We request the grant of a patent on the basis of this application.

Signature PAGE HARGRAVE Date 17/04/03

12. Name and daytime telephone number of person to contact in the United Kingdom **Craig Macpherson** **0117 927 6634**

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Medical Training System

The present invention relates to a medical training system.

One of the most fundamental and yet difficult examinations that students learn to perform in the first years of medical school is diagnosis through palpation. The theory of the examination can be learned from textbooks, CD ROM, lectures and observation of experts. While these methods of learning are helpful they does not provide the essential "hands-on" training which is required of a medical practitioner.

There are many soft sections of the body which all have the possibility of harbouring a mass, cyst or a growth, which in the early stages may be identified by means of external palpation. These soft sections can be found on the head, the neck and, in particular, a number of points on the torso, for example, the abdomen, the breasts, the testicles, the groin and the axilla [arm pit]. In addition, trainees are also called upon to identify the position of muscles, nodes, vessels, nerves, and other significant landmarks within the soft tissue structure of the body.

Traditionally students have relied upon examination of real patients who are within the hospital or clinical environment for the learning process. These patients are often uncomfortable and in pain. This can be dangerous and create further pain for the patient and it is also unpredictable, unreliable and variable. In order to objectively examine medical students multiple patients displaying specific conditions are required, and this is almost impossible to achieve.

In order to examine large numbers of medical sudents during a morning session or a day, a system called Objective Structured Clinical Examination [OSCE] has been established. Multiple patients are required for days on end within the Clinical Skills environment. If the skills to be examined are invasive, it is not only expensive but restrictive to use actors or volunteers as patients. Over the years actors, models, volunteers or fellow students (called patient simulators) have been employed for such activities. Unless by sheer chance one of these volunteers does indeed have a particular mass or masses within his or her body which can be identified and used for training, he or she is likely to have a normal body and not offer any of the abnormalities

which are required for experience for the trainee. The patient simulators are expensive and variable and as such draw continually on resources whilst not providing particularly realistic training.

The demands of training medical professionals are becoming more and more acute. Many countries need more doctors whilst each doctor is being asked to work fewer hours. Fewer patients are spending time in hospital due to the increase of day surgery and minimal invasive surgical techniques. These factors lead to less and less opportunity for the medical trainee to experience any "hands-on" diagnosis at all, let alone in a repetitive way. Unfortunately, litigation is now common due to medical malpractice, and the need to be able to train students comprehensively in clinical diagnosis through palpation is pressing.

In order to assist this difficult situation Clinical Skills Centres have been set up within or by medical training institutions. These centres are growing in number particularly in the western world, providing a safe environment to acquire "hands on" skills until competent. In most cases these centres have computer access and quite comprehensive training takes place.

As well as patient simulators in the form of human beings, a patient simulator in the form of a manikin which is connected to a computer is now well established. This manikin-based patient simulator requires a simulated "theatre environment". It is designed for procedural training as one finds in anaesthesia and some surgical practice.

Virtual reality is also well developed and it is particularly appropriate for training in endoscopic surgical procedures, and is convincing now that tactile feedback (haptics) has been achieved.

CD ROM based training is also well established and some of the products used are designed around a system of training on models.

Models and simulators are providing "hands-on" training at many levels; skills which are addressed cover simple skills such as knot-tying through to a quite complicated procedure of heart bypass operation.

Models also play an important role in augmented reality; specific instruments and a computer system are linked to scanned data and a model which has been designed and built from that data. Thus the procedure is performed on the model, and images on the screen or display are of the patient scans. These models can provide a very realistic simulation and provide a valuable teaching aid.

The aforementioned systems are all effective systems for training in skills, which, when put together make up a procedure. However, apart from feeling a pulse or listening to breathing sounds and heartbeats, there is no provision for training in diagnostic skills through palpation. Sophisticated manikins provide for training in Accident, Trauma and Emergency when feedback is provided according to the amount of pressure exerted in the case of resuscitation.

It is possible to construct various soft layers with lumps and masses of varying sizes between them and for the trainer and trainee to identify to what condition these lumps and masses relate. However, it is not possible for either the trainer or the trainee to be sure that the trainee has truly felt in the right place and has understood the approach to that part of the human body, or whether undue pressure has been exerted which would have caused pain or damage to the patient.

WO 02/19298 discloses a system for teaching medical examinations performed manually inside a body cavity or anatomical space. The system comprises a tactile sensor placed within an anatomical structure and is particularly intended to be used in pelvic and rectal examinations where the instructor cannot see the hands of the trainee performing the examination. The sensor is connected to a feedback presentation unit which allows the instructor to assess the examination.

US 5 957 694 discloses a canine abdominal palpation simulator for use by veterinary students in developing manual palpation skills. The simulator comprises a canine body with internal artificial organs connected to feedback devices controlled by switches. However, canine anatomy is significantly different from human anatomy and the techniques which students need to learn are different. In addition, the simulator merely provides an indication that a specific organ has

been palpated. There is no means for providing feedback as to the quality of the examination or whether the pressure exerted was appropriate.

According to a first aspect of the present invention there is provided a medical training system for examinations performed externally on the human body by manual palpation, said system comprising:

a simulation of a human anatomical structure, the anatomical structure having an outer surface and an internal cavity;

a simulation of an internal body structure in or for location in the internal cavity;

sensing means for generating a signal in response to external manual palpation of said simulated anatomical structure; and

a feedback presentation unit in communication with the sensing means for providing feedback to a user.

Preferably, the signal generated by the sensing means is in relation to the force of the external manual palpation.

The simulated internal body structure preferably comprises a simulated organ and/or a simulated soft tissue structure.

The internal body structure may suitably comprise a normal anatomy or an anatomy which has an abnormality which may be in the form of a cyst or a growth or an enlargement or a reduction. The enlargement may be a simulation of an internal body structure engorged with fluid. Advantageously, the system may be provided with a plurality of simulations of the same internal body structure, each one being of an increasing anatomical complexity and/or presenting increasing clinical difficulty, such that each simulation may be presented in turn for manual palpation to be practised on the system.

The simulated anatomical structure preferably comprises one or more of the following human anatomical structures: head, neck, shoulder, axilla, breast, torso, pelvis, knee or foot.

The sensing means preferably comprises a tactile sensor. The tactile sensor is preferably a force sensor. The sensor may be provided on an internal surface of the anatomical structure or on the surface of the simulated internal body structure or it may be embedded in the wall of the anatomical structure or the simulated internal body structure.

Preferably, the feedback presentation unit is adjustable to provide feedback for one of a plurality of different medical examinations. The examinations may comprise a set of predetermined steps and the feedback preferably provides an indication of completion of said set of steps.

The feedback presentation unit preferably comprises a display means which may suitably comprise a graphical display. The feedback presentation unit may conveniently be a PC. The feedback presentation unit preferably comprises a liquid crystal display and/or an analogue display.

According to a second aspect of the present invention there is provided a method of training examinations performed externally on the human body by manual palpation comprising the steps of:

receiving signals from the sensing means in a simulation of a human anatomical structure, wherein said signals are generated in response to external manual palpation of the structure; and

providing feedback to a user, wherein said feedback is in part derived from said signals.

According to a third aspect of the present invention there is provided a method of training examination performed externally on the human body by manual palpation, comprising the steps of:

providing a plurality of simulations of internal body structures, the simulations being a set of simulations of the same part of the anatomy and being of increasing anatomical complexity and/or presenting increasing clinical difficulty; and

presenting each of the simulations in turn within a simulated anatomical structure so that external manual palpation may be practised by a user.

The system according to the present invention may suitably be used in conjunction with EP 0 621 974 and EP 0 990 227, both of which are in the name of the present applicant. EP 0 621 974 relates to a simulation of body tissue comprising a member of elastomeric material overlying which is a simulated epidermis in the form of a relatively thin sheet comprising foam latex rubber. The simulated anatomical structure may suitably be covered with the simulated body tissue.

EP 0 990 227 relates to a skills training system comprising a plurality of simulations of body structures, the simulations being a set of simulations of the same part of the anatomy and being of increasing anatomical complexity and/or presenting increasing clinical or surgical difficulty. Means for receiving at least one of the simulations is provided so that each simulation can be presented in turn for a surgical and/or clinical technique to be practised on the simulation.

For a better understanding of the present invention, reference will now be made to the accompanying drawings, in which:

Fig. 1 shows a perspective view of a simulated human torso;

Fig. 2 shows a sectional view of a simulated organ within a simulated anatomical structure;

Fig. 3 shows a sectional view of a portion of a simulated human abdomen;

Fig. 4 shows a sectional view of a female human breast; and

Fig. 5 shows a partially cut away plan view of another simulated human torso.

Referring firstly to Fig. 1, this shows a medical training system 1 for examinations performed externally on the human body by manual palpation. Fig. 1 shows a perspective view of a simulation of an anatomical structure 2 in the form of a simulated human torso 4. The simulated torso 4 comprises an outer surface 6 in the form of a simulated skin layer and an internal cavity 8.

The internal cavity 8 simulates a human abdominal cavity and is provided with a plurality of mountings (not shown) onto which simulated internal body structures 10 may be fixed. The simulated internal body structures 10 may be in the form of simulated organs or other simulated soft tissue structures such as muscles, nodes, vessels and nerves. Such soft tissue structures should slide across one another in a realistic way - being made of materials which allow surfaces to move easily across one another. The cavity 8 closely resembles a human abdominal cavity in size and shape and the location of the mountings is such that the position of the internal body structures 10 is anatomically correct. The internal body structures 10 are removable and replaceable and it is envisaged that the system will be provided with a plurality of simulations of the same internal body structures 10, each one being of an increasing anatomical complexity and/or presenting increasing clinical difficulty, such that each simulation may be provided in turn for manual palpation to be practised on the system 1. For example, a plurality of simulations of the same organ may be provided, each one having a larger abnormal growth than the previous one. A system such as this enables a user to gain experience in a variety of situations and provides a means for distinguishing between a healthy body and one with an abnormality or growth.

A plurality of tactile sensors 12a-12g are located within the cavity 8. The sensors 12a-12g are force sensing resistors which generate a signal in response to a force being exerted externally, on the outer surface 6 of the anatomical structure 2. The size of the signal is related to the pressure exerted. Any suitable sensor which can generate a signal in response to the application of an external force may be used.

The system 1 also comprises a feedback presentation unit 14 in communication with the tactile sensors 12. The feedback presentation unit 14 has a display screen 16 and provides information regarding the quality of the examination. The feedback presentation unit 14 can provide visual information on whether the user has felt in the correct place and whether the correct pressure has been exerted. Alternatively, the feedback display unit 14 may provide other types of feedback, for example, auditory, tactile or some other indication.

In Fig. 1 the anatomical structure 2 is in the form of a human torso 4. However, this is merely one embodiment of the invention and the anatomical structure 2 may in fact be in the form of any human anatomical structure which may be subjected to external manual palpation. The anatomical structure 2 may be in the form of one or more of the following human anatomical structures: head, neck, shoulder, axilla, breast, torso, pelvis, knee, foot or other area of the human body. The individual anatomical structures 2 may be stand alone models upon which specific examinations may be practised or they may be modular units which may be combined together to form a single larger model. Similarly, the simulated internal body structures 10 may be in the form of any internal body structure which may be examined by external manual palpation.

The plurality of sensors 12a-12g are provided within the cavity 8. The sensors 12a-12g are provided at specific locations selected to gather information relating to the quality of the examination. Sensors 12a, 12b and 12c are located on the internal wall of the cavity 8 and sensors 12d, 12e, 12f and 12g are located on the internal body structures 10. The sensors 12 are preferably embedded within the structure on which they are located. This prevents the sensors 12 from becoming dislodged through repeated use.

In addition to the use of sensors 12 in the form of force sensing resistors the internal body structures 10 themselves may act as sensors. This may be achieved by filling some or all of the internal body structures 10, such as the simulated organs, with a known amount of a liquid or gas. The liquid or gas filled internal body structures 10 are then connected, by means of a length of tubing, to a pressure measurement device. When pressure is applied to the outer surface of the anatomical structure 2, by means of external manual palpation, some of the liquid or gas will be forced out of the internal body structures 10. This will enable measurements to be taken to

determine the force applied and whether it was appropriate to the particular examination being performed. The results may be displayed in any suitable manner by the feedback presentation unit 14.

The feedback presentation unit 14 has a processor which processes the information from the sensors 12 and provides an indication of the quality of the exam. The processor may suitably be configured to provide feedback on a specific examination type. For example, in the simulated human torso 4 of Fig. 1 there are a number of simulated internal body structures 10 within the cavity 8 which may be examined individually. However, examination of one internal body structure 10 may result in an incidental force being exerted on another internal body structure 10. The system 1 may be set up for a number of different exams and the processor will interpret the signals form the sensors 12 depending on the exam type. The signal generated by the sensors 12 is in direct relationship to the size of the external force exerted. Consequently, the processor can determine whether the appropriate pressure has been applied.

The processor may also include comparative data corresponding to a correctly performed examination. This enables the performance of a user to be compared to a consistent reference point and enables feedback to be provided whilst the examination is being performed.

Referring now to Fig. 2, this shows a sectional view of a simulated internal body structure 10 in the form of a simulated organ 16 provided within an internal cavity 8 of a simulated anatomical structure 2. The internal body structure 10 may be a simulation of any soft tissue structure of the human body. Fig. 2 shows an examination being performed externally on the human body by manual palpation. A force is applied manually to the outer surface 6 of the anatomical structure 2 and this is detected by a plurality of sensors 12h, 12i and 12j located within the anatomical structure 2. A first sensor 12h is located under the surface of the outer simulated skin layer. A second sensor 12i is located on the internal surface of the anatomical structure 2 and, as can be seen in Fig. 2, this sensor 12i comes into contact with the simulated organ 16 when an external force is applied to the anatomical structure 2. A third sensor 12j is embedded within the simulated organ 16. The sensors 12 may be located at any suitable position in order to detect

external palpation. They may be on the internal structure of the anatomical structure 2 or on an outer surface of an internal body structure 10 or wedged between the two.

Fig. 3 shows a sectional view of a portion of a simulated human abdomen 18. Sensors 12 are located in the abdomen wall, on the internal surface of the abdomen wall and on the surface of simulated internal body structures 10.

Fig. 4 shows a sectional view of a simulated female breast 20. The breast 20 is filled with a material 22 which gives the breast 20 a realistic appearance and feel. Abnormalities 24, 26 are provided within the structure of the breast 20. The abnormalities may be in the form of simulated cysts or tumours which enable breast examination techniques to be practised. A plurality of sensors 12 are provided within the structure of the breast 20 including sensors 12 provided on each of the abnormal growths 24, 26. As previously described, a signal will be generated when a force is applied by means of external manual palpation.. It is intended that the breast model could be provided with a plurality of inserts, each one being of increasing difficulty or displaying a more developed growth.

Fig. 5 shows a partially cut away view of an alternative embodiment of a simulated anatomical structure 2 in the form of a torso 4. The torso 4 comprises a mechanical diaphragm which can operate to simulate a breathing movement within the torso 4. The mechanical diaphragm comprises a pressure plate 30 which is linearly actuable as indicated by arrow A. Movement of the pressure plate 30 as indicated causes compression of the air within the internal cavity 8 of the torso 4 and provides a simulation of a breathing movement. The pressure plate 30 is connected to actuating means 32 which may be a mechanical or foot activated bellows, pump, piston or any other suitable actuating means.

In addition to providing improved visual realism the mechanical diaphragm simulates the effect which breathing has on the internal organs, thus providing improved anatomical realism.

CLAIMS

1. A medical training system for examinations performed externally on the human body by manual palpation, said system comprising:

a simulation of a human anatomical structure, the anatomical structure having an outer surface and an internal cavity;

a simulation of an internal body structure in or for location in the internal cavity;

sensing means for generating a signal in response to external manual palpation of said simulated anatomical structure; and

a feedback presentation unit in communication with the sensing means for providing feedback to a user.

2. A system according to claim 1, wherein the signal generated by the sensing means is in relation to the force of the external manual palpation.

3. A system according to claim 1 or claim 2, wherein the simulated internal body structure comprises a simulated organ.

4. A system according to any one of claims 1-3, wherein the simulated internal body structure comprises a simulated soft tissue structure.

5. A system according to any preceding claim, wherein at least one internal body structure comprises an abnormality.

6. A system according to claim 5, wherein the abnormality is in the form of a cyst or growth or enlargement or reduction.

7. A system according to any preceding claim, wherein a plurality of simulations of the same internal body structure are provided, each one being an increasing anatomical complexity and/or presenting increasing clinical difficulty, such that each simulation may be presented in turn for manual palpation to be practised on the system.

8. A system according to any preceding claim, wherein the anatomical structure comprises a human torso.

9. A system according to any preceding claim, wherein the anatomical structure comprises a female breast.

10. A system according to any preceding claim, wherein the anatomical structure comprises a human head.

11. A system according to any preceding claim, wherein the anatomical structure comprises a human neck.

12. A system according to any preceding claim, wherein the sensing means comprises a tactile sensor.

13. A system according to claim 12, wherein the tactile sensor is a force sensing resistor.

14. A system according to claim 12 or claim 13, wherein the sensor is provided on an internal surface of the anatomical structure.

15. A system according to any one of claims 12-14, wherein the sensor is provided on the surface of the simulated internal body structure.

16. A system according to any one of claims 12-15, wherein the sensor is provided embedded in the simulated internal body structure.

17. A system according to any preceding claim, wherein said simulation and said feedback presentation unit are adjustable to provide feedback for one of a plurality of different medical examinations.

18. A system according to any preceding claim, wherein said medical examination comprises a set of predetermined steps and said feedback comprises an indication of completion of said set of predetermined steps.

19 A system according to any preceding claim, wherein the feedback presentation unit comprises a display means.

20. A system according to claim 19, wherein said display means comprises a graphical display.

21. A system according to any preceding claim, wherein said feedback presentation unit comprises a liquid crystal display.

22. A system according to any preceding claim, wherein said feedback presentation unit is an analogue display unit.

23. A method of training examinations performed externally on the human body by manual palpation comprising the steps of:

receiving signals from the sensing means in a simulation of a human anatomical structure, wherein said signals are generated in response to external manual palpation of the structure; and

providing feedback to a user, wherein said feedback is in part derived from said signals.

24. A method of training examination performed externally on the human body by external manual palpation using a system according to any one of claims 1-22, comprising the steps of:

providing a plurality of simulations of internal body structures, the simulations being a set of simulations of the same part of the anatomy and being of increasing anatomical complexity and/or presenting increasing clinical difficulty; and

presenting each of the simulations in turn within a simulated anatomical structure so that external manual palpation may be practised by a user.

25. A system substantially as hereinbefore described with reference to the accompanying drawings.

26. A method substantially as hereinbefore described with reference to the accompanying drawings.

ABSTRACT

A medical training system (1) for examinations performed externally on the human body by manual palpation, said system comprising:

a simulation of a human anatomical structure (2), the anatomical structure (2) having an outer surface (6) and an internal cavity (8);

a simulation of an internal body structure (10) in or for location in the internal cavity (8);

sensing means (12) for generating a signal in response to external manual palpation of said simulated anatomical structure (2); and

a feedback presentation unit (14) in communication with the sensor (12) for providing feedback to a user.

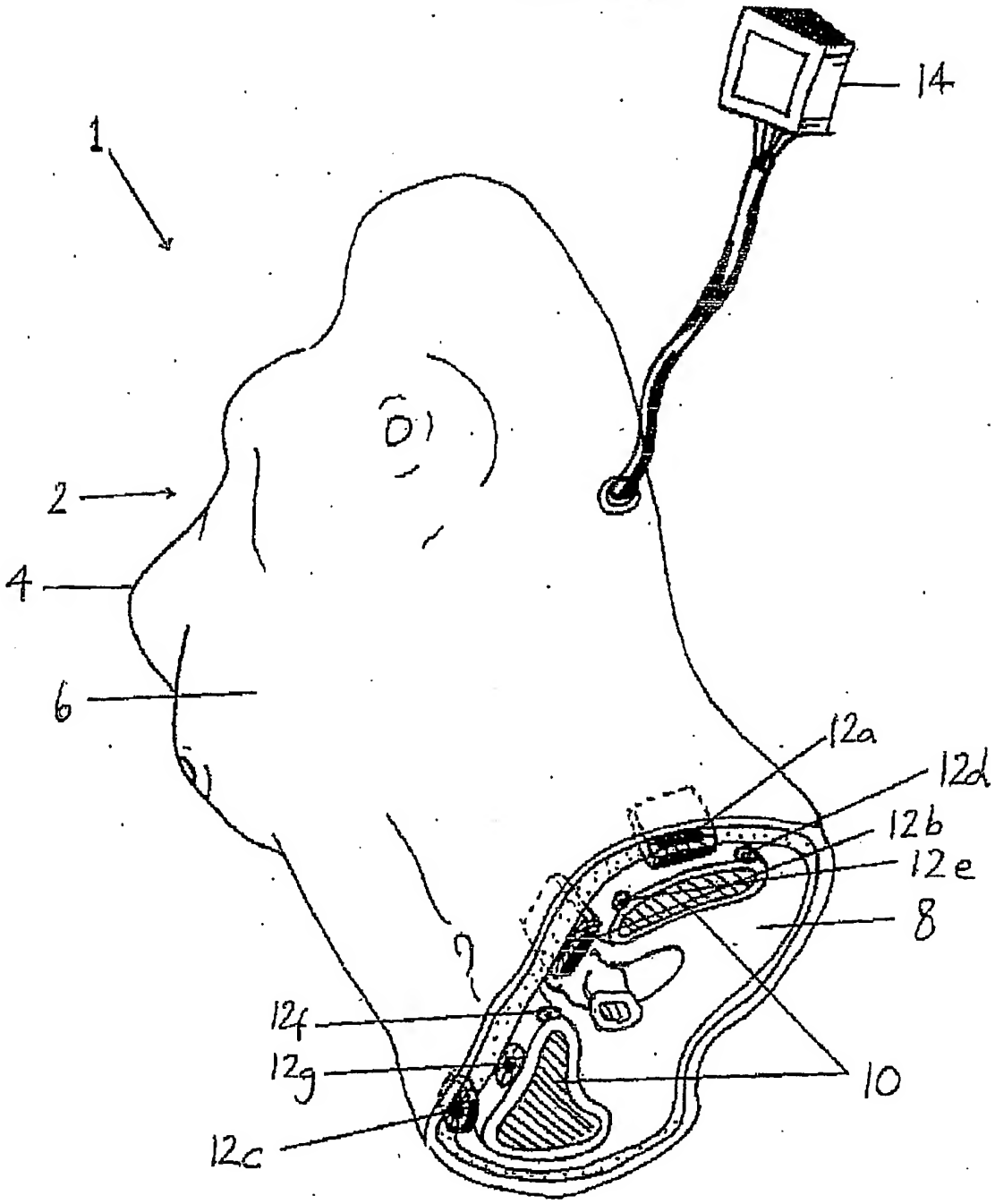


Fig. 1

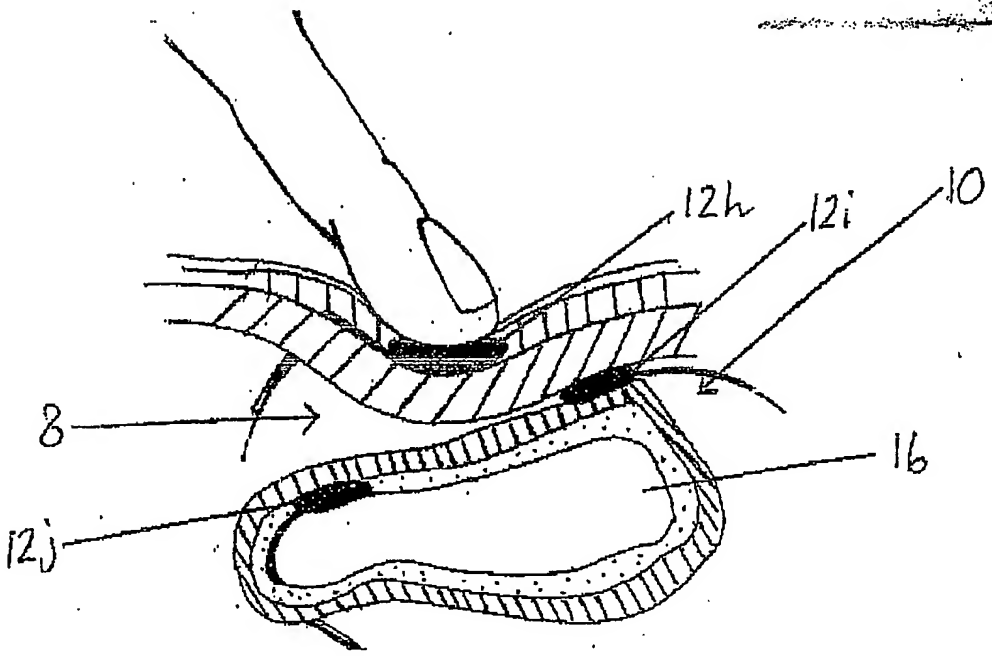


Fig. 2

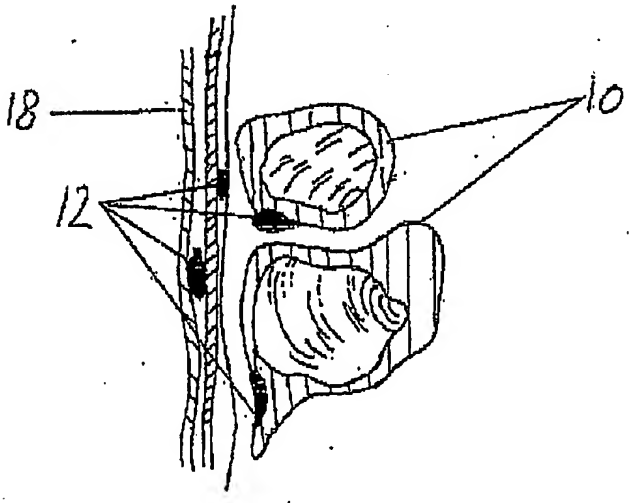


Fig. 3

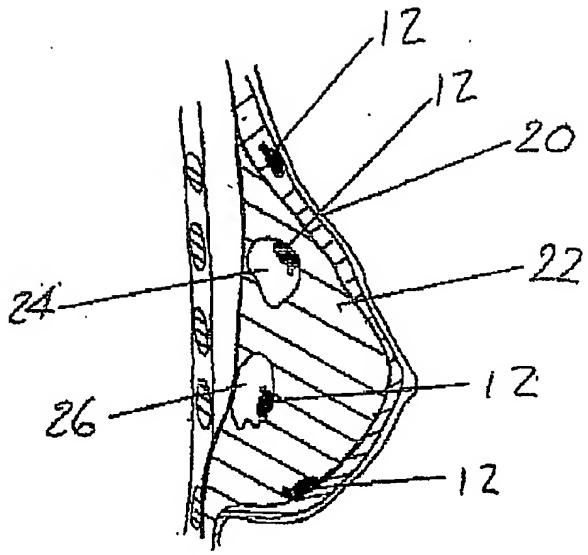
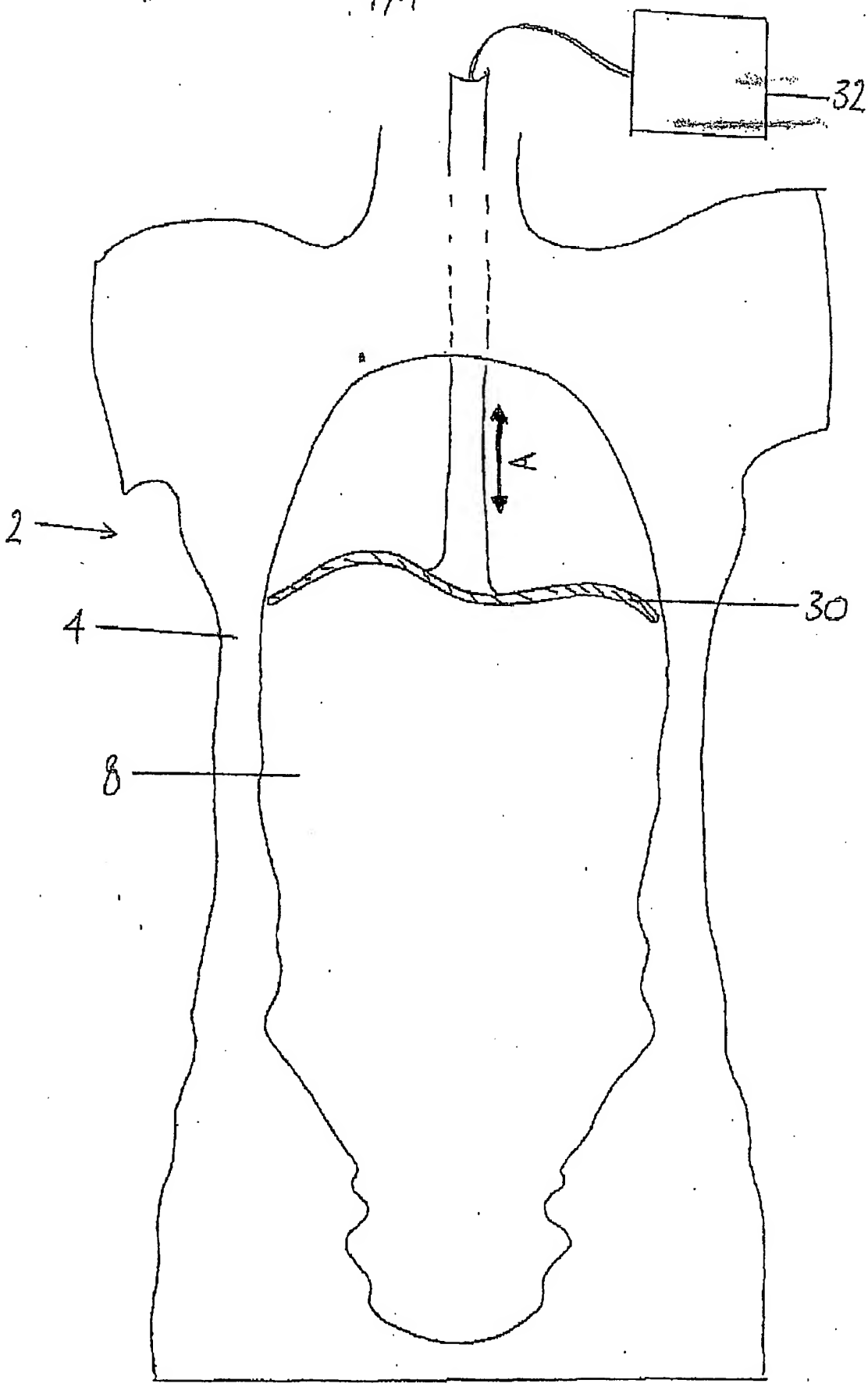


Fig. 4

4/4



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